H. Provider-Sponsored Organizations (Subpart H)

Among the new options available to Medicare beneficiaries is enrollment in a provider-sponsored organization (PSO). A PSO is described in section 1855(d) of the Act as a public or private entity--

- That is established or organized, and operated, by a health care provider or group of affiliated health care providers;
- That provides a substantial portion of the health care items and services directly through the provider or affiliated group of providers; and
- With respect to which the affiliated providers share, directly or indirectly, substantial financial risk for the provision of these items and services, and have at least a majority financial interest in the entity.

The PSO regulations at §§422.350 through 422.390 include definitions, solvency standards (developed through negotiated rule making), and waiver requirements that have been established through three previous Federal Register publications. On April 14, 1999, we published an interim final rule with comment, titled "Definition of Provider-Sponsored Organization and Related Requirements" (63 FR 18124), setting forth the PSO definition, clarifying certain terms, and establishing related requirements. On May 7, 1998, we published an interim final rule with comment,

titled "Waiver Requirements and Solvency Standards for Provider Sponsored Organizations" (63 FR 25360), establishing solvency requirements that apply to PSOs that obtain a waiver of the M+C State licensure requirements, and setting forth procedures and standards that apply to requests for the waivers. The solvency portion of the PSO regulation was based on the work of the PSO negotiated rulemaking committee, as required at section 1856(a) of the Act. On December 22, 1999, we published a final rule titled "Solvency Standards for Provider-Sponsored Organizations" (64 FR 71673), that addressed the comments we received on the PSO solvency standards and waiver requirements. In this final rule, we are responding to comments on the April 14, 1998 PSO definitions interim final rule.

Comment: A commenter believes that the interim final rule did not sufficiently ensure that a PSO is actually controlled by providers. Another commenter thinks that effective control is defined too loosely in the regulation.

Response: We believe that the existing regulatory requirements are sufficient to ensure that PSOs are organizations that are owned and controlled by health care providers. Among the basic requirements for PSOs at §422.352(a)(3) is the requirement that to be considered a PSO for purposes of the Medicare+Choice program, an organization must be controlled by a health care provider or, in the case of a group, by one or more

of the affiliated providers that established and operate the PSO. Under the definitions at §422.350(b), we define control as meaning "that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution." This definition is essentially the same as the long-standing definition of control that is used for purposes of providers in the Medicare fee-for-service program (see §413.17). We believe that the general definition for control we have adopted, which will result in case-by-case determinations by us, will ensure that PSOs are controlled by providers.

Comment: A commenter requested that we exempt PSOs formed by community health centers from the requirement in §422.352(b)(1) that a non-rural PSO must deliver 70 percent of the health care services and items through the provider or affiliated providers responsible for running the PSO.

Response: We do not believe that a special exemption from §422.352(b)(1) for community health centers is warranted. As we will note below, we do allow a lower percentage of health care services delivery for rural PSOs as compared to non-rural PSOs. However, because the percentage of health services delivery is in part designed to ensure that the PSO will remain solvent, we believe it would not be prudent to reduce the percentage for different types of organizations such as community health

centers. To put our response in perspective, we will briefly discuss the PSO requirement that the PSO providers deliver a substantial proportion of health care services, and the reasons we have selected 70 percent for non-rural PSOs and 60 percent for rural PSOs.

The M+C regulations at §422.352(b) specify that a PSO must deliver a substantial proportion of the health care items and services through the provider or affiliated group of providers responsible for operating the PSO. We have concluded that setting the substantial proportion requirement at 70 percent for a non-rural PSOs and 60 percent for rural PSOs balances two key interests. These interests are, specifically: (1) that we not set the proportion of services so high as to prevent participation by all but the most sophisticated provider organizations; and (2) that the substantial proportion threshold be sufficient to ensure that a PSO have a well-developed capacity to deliver services, thus meeting the financial stability objective explicit in the statute, and increasing the prospects for successful development and solvent operation of a PSO. There is no indication in the PSO provisions in Part C that the Congress intended that a different standard be applied to community health centers, or any other entity. We see no basis for doing so.

Comment: A commenter recommends that we measure substantial proportion based on encounters rather than expenditures.

Response: As discussed in the previous response, §422.352(b) requires that a PSO deliver a substantial proportion of the health care items and services through the providers or affiliated providers responsible for operating the PSO. In calculating the substantial proportion percentage, we considered what would be the best method for comparing the proportion of items and services furnished by a PSO-affiliated provider with the overall amount of items and services furnished through the PSO. The two possible approaches we identified involved either the use of Medicare encounter data or Medicare expenditure data. Based on discussions with the health care industry, we learned that using expenditure data generally would not be burdensome for PSOs, because it is already commonly collected for management purposes. Furthermore, expenditure data may also produce a measurement more in line with the intent of the substantial proportion requirement. For example, the expenditures associated with an acute hospital visit would reflect a higher draw upon the PSO’s resources than a physician office visit. Likewise, with expenditure data, the dollar amounts associated with each physician office visit, home care visit, etc., will reflect resource use and the ability of PSO providers to manage medical utilization. Therefore, based upon its immediate availability

and arguably greater relevance and significance, we have concluded that use of expenditure data is the better approach for determining compliance with the substantial proportion requirement.

Comment: A commenter recommended changing the language in §422.376 from "the waiver is effective for 36 months, or through the end of the calendar year in which the 36 months period ends" to "the waiver is effective for 36 months."

Response: We do not believe it is appropriate, as suggested by the commenter, to change §422.376(b) so that it reads, "the waiver is effective for 36 months." The reason we have chosen to allow a waiver to remain in effect until the end of the calendar year in which the 36 month period ends is that this ensures that the PSO's Medicare contract also remains in effect through the calendar year. To do otherwise could require a mid-year contract termination with significant disruption for beneficiaries enrolled in the PSO.